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Being a modern pharmaceutical company

Involves making information available on clinical trial programmes

What does it mean to be a modern pharmaceutical company? Rapid changes in society and advances in science and medicine mean that the pharmaceutical industry has several important roles today that would not have been apparent as recently as 10-15 years ago. To provide medicines of value the modern pharmaceutical company has to meet the needs of patients for better medicines while taking full account of the realities of healthcare economics. It has to harness scientific advances, particularly in genetics and information technology, and work in partnership with researchers, healthcare providers, and governments. One substantial outcome of these partnerships is a better understanding of the need for openness and transparency in clinical trials.

For healthcare providers the cost of health care is a paramount issue, and the industry knows that new medicines have to deliver real benefits over existing ones. Delivering better medicines—demonstrated by the right clinical studies, with the right comparators and demonstration of appropriate dosages and use—is exciting but is accompanied by dilemmas which have to be faced and resolved. Society expects the industry to behave responsibly and to disclose information whenever possible.

Decision makers clearly want more access to information on clinical trials. Our industry is based on a rigorous process of conducting, analysing, and reporting clinical trials—a task we undertake as part of the regulatory approval system. By law we are required to include all trials involving a product in the regulatory submission for that product. The problem for decision makers and prescribers is that much of this information is not in the public domain. We have traditionally relied on a long established process of submitting trials to peer reviewed journals as a way of presenting data to the medical and healthcare communities. That process of peer review is important and should continue, but we can certainly improve on the timeliness and tracking of information and help avoid bias in reporting clinical trial data. The internet offers great scope for disclosing information: it is searchable, quick to access, and has global reach.

GlaxoWellcome has introduced a policy of registering information on its future clinical trials programmes. The objective of this policy is to help those undertaking systematic reviews of clinical data and to help reduce the impact of publication bias.^{1 2} We have committed to register clinical trial protocols so that they are accessible to healthcare professionals and researchers outside the company. Our policy applies to

all studies undertaken by GlaxoWellcome worldwide. In future, protocols for completed phase II and III studies will be registered around the time of regulatory approval and the register will then be updated at least annually with protocols for our largescale phase IIIb and IV studies. The first trial details are available on a password protected area of the new GlaxoWellcome external research and development website (science.glaxowellcome.com).

We have also committed to publishing all clinical trials, as far as this is possible, and will assign a unique identifier to each trial which may be included in all subsequent publications. This will help those undertaking systematic reviews to identify duplicate publications and thus avoid any impact this might have on the estimation of efficacy via meta-analysis.³

Pharmaceutical companies cannot, however, solve the problem of publication bias alone. All those undertaking research need to make similar commitments—indeed the recent guidelines from Britain's Medical Research Council on the performance of clinical trials highlight the need to publish the results of all studies.⁴ The editors of medical journals also have an important role, and progress in electronic publishing would increase the speed of publication and reduce the potential for lack of space to influence the inclusion of a study.

Disclosure of clinical trials may have additional benefits. The reorganised NHS research and development programme has concentrated research funding in Britain on areas important to the NHS itself. A comprehensive register of clinical trials will improve communication about what research is taking place, so that duplication can be avoided and resources used more effectively.

GlaxoWellcome has taken the lead in disclosure of information, and I hope that the rest of the pharmaceutical industry will join this initiative. As a knowledge based industry we understand well the value of information, and we want to create a climate of openness where the evidence for prescribing our products is clear.

Richard Sykes *Chairman*

GlaxoWellcome, Greenford, Middlesex UB6 0NN

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